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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,417	08/08/2001	Azariah Jossifoff	6727/0J367US	7902

7278 7590 07/28/2004

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,417

Applicant(s)

JOSSIOFF, AZARIAH

Examiner

Alton N. Pryor

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 52-97, 100 and 104-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 52-54 and 104-108 is/are allowed.
- 6) ☐ Claim(s) 55, 56, 86-97, 100 and 109-112 is/are rejected.
- 7) ☐ Claim(s) 57-85, 90 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Rejection of claims 71,91 under 35 USC 112 will not be maintained. Applicant amended claims to exclude range with in a range claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 100 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 100 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What is meant by term "substantially"?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 55,56,86-97, 109-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roser et al (US 5958455; 9/28/99). Roser teaches an effervescent tablet that can comprise progesterone, trehalose (non-effervescent) and sodium carbonate and tartaric or citric acid (effervescent). See column 2, column 5 lines 11-23, column 11 lines 62-65, column 12 lines 4-13. Roser teaches that the tablet can be made in a variety of ways. For example, the tablet can be made by combining components in solution or suspension in an aqueous solvent to form a homogenous powder and then form tablets from the powder. In this version of preparation, excipients are added to the aqueous solvent or added to the powder. The active ingredient such as progesterone and trehalose are added to the solvent. See column 7 line 61 – column 8 line 15. Roser teaches several other ways to make the tablet. For example, another way is to combine trehalose, active, and excipients in the powder to form a homogeneous mixture and form tablets from the mixture. See column 8 lines 30-37. Roser also teaches another way to make the tablet involving mixing active solution with trehalose, drying the mixture and then subjecting the dried mixture to heat and vacuum prior to tablet formation. See column 8 lines 38-63. Roser does not teach using micronized progesterone and the exact ordering of steps of tablet formulation of the instant claims. It would have been obvious to one having ordinary skill in the art to determine the optimum particle size of progesterone. One would have been motivated to do this in order to develop the most effective tablet for progesterone delivery to a female. It would have been obvious to one having ordinary skill in the art to have made the progesterone tablet by the instant method of preparation. One would have been motivated to do this since Roser teaches

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that the tablet can be made by a number of processes which includes the preparation steps to the instant claims. In a claim to a preparation a change in the ordering of the steps are not significant without the support of unexpected results.

Allowable Subject Matter

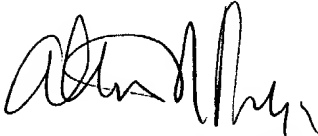
Claims 57-85,90 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 52-54,104-108 are allowable. The prior art does not teach or suggest the instant method wherein a lubricant is sieved. The prior art does not teach or suggest a method of placing in the vagina the instant progesterone tablet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Kunz can be reached on 571-272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

A handwritten signature in black ink, appearing to read 'Alton Pryor'.

Alton Pryor, AU 1616
July 19, 2004

Primary Examiner